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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,633	02/12/2001	Yasuo Motoyama	MOTOYAMA I	9666

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/762,633

Applicant(s)

MOTOYAMA ET AL.

Examiner

Juliet C Einsmann

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This correspondence is written in response to applicant's after final amendment filed 7/25/02 (paper number 15). All previous claims were cancelled, and claim 13 was added. The finality of the office action mailed 6/6/02 (paper number 14) is hereby withdrawn.

2. The examiner handling this application has changed. Please address all future correspondence to Examiner Juliet Einsmann.

#### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 does not include any language that indicates the claimed nucleic acid is and or purified from its natural source. Because the claim reads on polynucleotides that would occur in nature, untouched by the hand of man, this claim, as broadly drawn, encompasses non-statutory subject matter. This rejection may be overcome by amendment of the claims to include, for example, language clarifying that the claimed nucleic acids are intended to be isolated and/or purified nucleic acids.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite over the recitation "A gene sequence of a spacer region" because it is not clear if the claim intended to be drawn to a nucleic acid which comprises the spacer region between a gene coding 16S rRNA and a gene coding 23S rRNA of *Pectinatus cerevisiiphilis* OR if the claim is intended to be drawn to a nucleic acid comprising some "gene" that may be within the spacer region. The term "gene" is a term of art that designates a section of nucleic acid that encodes a polypeptide, but the claim appears to be drawn to a region between two genes, and not a gene per se, thus the claim is indefinite.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection applies to claim 13 when it is interpreted to be claiming a "gene" that is located within SEQ ID NO: 3 (see 112 2<sup>nd</sup> rejection). Applicant has not provided any description for a gene (i.e. a nucleic acid that encodes a particular polypeptide) that is contained within SEQ ID NO: 3. It appears from the specification that SEQ ID NO: 3 comprises the spacer region between two genes and thus contains only non-coding sequence. As such, the specification does

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not provide descriptive support for a "gene" contained within SEQ ID NO: 3, as is currently claimed.

#### ***Election/Restrictions***

8. The previously set forth restriction requirement is hereby withdrawn, in part. Product claims that are drawn to isolated nucleic acids that are fragments of SEQ ID NO: 3 are rejoined to SEQ ID NO: 3. Specifically, nucleic acids disclosed as SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 9 are fragments of SEQ ID NO: 3. Any claims drawn to SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9 are hereby rejoined to claim 13. This rejoinder does not include all nucleic acids from *Pectinatus cerevisiiphilus*, because SEQ ID NO: 4 is not a sub-fragment of SEQ ID NO: 3, as it contains mismatches when compared to SEQ ID NO: 3. Thus, SEQ ID NO: 4 is a separate invention from SEQ ID NO: 3 as stated in the original restriction requirement. The examiner acknowledges that no such claims are currently pending in this application, however, claims limited to fragments of SEQ ID NO: 3 were set forth, these would not be restricted away from claim 13. Applicant is reminded that originally examined claim 3 contained generic language encompassing fragments of SEQ ID NO: 3 and was rejected over the prior art.

#### ***Allowable Subject Matter***

9. The following claim would be allowable: "An isolated nucleic acid that is the spacer region between a gene encoding the 16S rRNA and the gene encoding the 23S rRNA of *Pectinatus cerevisiiphilus*, wherein said isolated nucleic acid comprises SEQ ID NO: 3."

Alternatively, the claim "An isolated nucleic acid comprising SEQ ID NO: 3." would also be allowable.

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10. The prior art does not teach or suggest an isolated nucleic acid comprising instant SEQ ID NO: 3.


*Conclusion*


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 21, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

  
Juliet C. Einsmann  
Examiner  
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